UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,473	11/30/2004	Hendrik Sibolt Van Damme	65959/47	5738

1912 7590 10/02/2007

AMSTER, ROTHSTEIN & EBENSTEIN LLP
90 PARK AVENUE
NEW YORK, NY 10016

EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,473	VAN DAMME ET AL.	
	Examiner	Art Unit	
	Paul C. Martin	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 November 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/04, 8/2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 are pending in this application.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-25 and amended Claims 26-31) in the reply filed on 08/02/07 is acknowledged. Claims 26-31 are acknowledged as being drawn to the subject matter of Claims 1-25 and are rejoined.

Applicant's election with traverse of the species (cellular components: microbial cells), (detector molecules: specific dyes), (cellular responses: growth inhibition) and (molecule of interest: small organic molecules including pharmaceutical molecules) in the reply filed on 08/02/07 is acknowledged. The traversal is on the ground(s) that it would not place an undue burden on the Examiner to examine both microbial cells and mammalian cells. This is not found persuasive because microbial cells and mammalian cells are independent and distinct from one another in terms of both structure and function, the two groups being recognized as different on the macroscopic level, mammalian cells being eukaryotic and microbial cells being typically prokaryotic. A search for mammalian cells would not therefore be co-extensive with a search for microbial cells and the restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-31 were examined on their merits.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 11/30/04 and 08/02/07 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

The information disclosure statement filed 11/30/04 fails to fully comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

The use of the trademarks OREGON GREEN™, TEXAS RED™ and BODIPY™ has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

The informal drawings 2A, 2B and 3B are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 5B lacks the "B".

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s).

See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 8-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 8-18 and 20-28 of copending Application No. 10/579,896. Although the conflicting claims are not identical, they are not patentably distinct from each other because one of ordinary skill in the art at the time of the instant invention would have recognized that the differences between the method of the '896 application and the instant application are that the

porous solid support has a fist and second surfaces and a supply chamber at the first and/or second surface and opposite the cellular components for the delivery of effectors to the cellular components. One of ordinary skill in the art would have recognized that the duplication of parts, i.e., surfaces is not sufficient to demonstrate non-obviousness. The MPEP states:

> *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (Claims at issue were directed to a water-tight masonry structure wherein a water seal of flexible material fills the joints which form between adjacent pours of concrete. The claimed water seal has a "web" which lies ** in the joint, and a plurality of "ribs" ** >projecting outwardly from each side of the web into one of the adjacent concrete slabs. <The prior art disclosed a flexible water stop for preventing passage of water between masses of concrete in the shape of a plus sign (+). Although the reference did not disclose a plurality of ribs, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.).

Further, one of ordinary skill in the art would have recognized that a supply chamber to contain the effectors (or test compounds) through the porous solid support would have been obvious as the instant application utilizes a similar porous solid support and merely indicates that the test are delivered to positions on the substrate. One of ordinary skill in the art would have been aware that either of two mechanisms could deliver the test compounds/effectors to the cellular components on the substrate, from below and through the porous solid substrate or from above directly onto the cellular components. As the instant application is silent as to what means of delivery is utilized, one of ordinary skill in the art would have recognized the obviousness of the below method taught in the '896 application.

Claims 2-5 and 8-22 of the instant application are substantial duplicates of Claims 6, 8-18 and 20-28 of the '896 application. The claims correspond in this fashion with the claims of '896 being enclosed in parentheses; Instant Claims 2 (23), 3 (11), 4 (9), 5 (10), 8 (18), 9 (20), 10 (20), 11 (21), 12 (22), 13 (12), 14 (13), 15 (14), 16 (6), 17 (16), 18 (17), 19 (24, 25), 20 (26), 21 (27) and 22 (28).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 17-31 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

In the instant case, the claims are drawn to a method of screening of cellular responses of cellular components, comprising arraying cellular components on the surface of a porous substrate containing detector molecules within the pores, delivering test compounds to positions on the substrate corresponding to the detector molecules and assaying for cellular responses of the cellular components.

(1) Level of skill and knowledge in the art:

The level of skill in the art is deemed to be high, however even those of skill in the art would not have sufficient guidance or knowledge to determine that the Inventor had possession of every 1) cellular response, ranging from cell growth, meiosis, apoptosis, protein secretion, motion (taxis), etc., of any 2) cell or cellular component which would be innumerable, ranging from every plant, animal, bacterial, viral, fungal species on earth and each and every component contained therein, said response being detected, 3) by any of innumerable detector molecules encompassed by the claims.

(2) Partial structure:

The Applicant has not provided structures or structural data for each and every cellular component, cellular response or detector molecule which has applicability to the instant invention.

(3) Physical and/or chemical properties:

The Applicant has not provided the physical and/or chemical properties or characteristics of each and every cellular component, cellular response or detector molecule which has applicability to the instant invention.

The Applicant only broadly lists broad classes of cellular components, cellular responses and detector molecules as useful in the claimed invention.

(4) Functional characteristics:

Similarly, the Applicant has not provided the functional characteristics of each and every cellular component, cellular response or detector molecule which has applicability to the instant invention.

(5) Method of making the claimed invention:

The Applicant has not provided sufficient guidance or teachings to allow one of ordinary skill in the art to make the claimed invention beyond the limited specificity of the examples. The broadly claimed invention encompasses innumerable embodiments which would necessarily be inoperable based on the combination of any random cellular component being assayed for any cellular response by any random detector molecule.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad genus. Claim 1 is broadly generic to all possible cellular components, cellular responses and detector molecules encompassed by the claims. The possible variations are enormous to any class of cellular components, cellular responses and detector molecules.

Since the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of cellular component/cellular response/detector molecule beyond those disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of cellular components beyond those found on Pg. 10-12,15, 18 and 19 of the instant specification.

While having written description of the cellular components, cellular responses and detector molecules identified in the specification and/or examples, the specification is devoid of any other cellular components, cellular responses or detector molecules that qualify for the functional characteristics claimed.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the screening of cell growth of transformed bacterial cells in response to antibiotics using visual inspection and light microscopy; the detection of enzyme activity in transformed bacterial cells or mammalian cells using a fluorescent enzyme substrate in response to antibiotics; the detection of reporter gene expression or transformed bacteria in response to antibiotics; the screening of animal and bacterial cell lysate by antibodies; and the growth of filamentous fungi on the porous substrate, does not reasonably provide enablement for a method of screening any cellular response from any cellular component using any detector molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There is no guidance or direction presented to direct one to determine which substances would work in the broadly claimed invention, which is a complex and unpredictable art. Therefore, because of the large number of inoperable embodiments claimed, the ordinary artisan would be subjected to undue experimentation to practice the claimed invention. The enablement is not commensurate in scope with claims drawn to a method of assaying any cellular response from any cellular component using any detector molecule.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed. The Applicant's disclosure broadly defines cellular components as mammalian, insect, yeast, plant or bacterial cells, cellular vesicles, cellular organelles, tissue sections and whole microscopic organisms (Pg. 10, Lines 26-29). The disclosure also indicates that cellular responses can be induced or physiological events such as lysis, apoptosis, growth inhibition/promotion, production/secretion/or surface expression of a protein or other molecule of interest by a cell, membrane surface molecule activation including receptor activation, trans-membrane ion transports and transcriptional regulations, changes in intracellular ion fluxes, pH, temperature, and transmembrane potential (Pg. 16, Lines 26-31 and Pg. 15, Lines 7-12), and that detector molecules may be in the form of nucleic acids including modified analogues thereof, peptides, proteins, antibodies and fragments thereof, enzyme substrates and dyes (Pg. 18, Lines 20-24).

2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work. The disclosure merely lists and describes broad classes of unrelated cells which may or may not be capable of exhibiting any of a broad range of cellular responses to unspecified test compounds which may be somehow detected by unspecified detector molecules. Short of testing every possible combination of cell/component for every possible response using every possible detector compound one of ordinary skill in the art would not be able to make and use the instant invention to the full scope of the claims.

3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested. The working examples are directed (those meeting the specific method steps of Claim 1) to the screening of cell growth of transformed bacterial cells in response to antibiotics using visual inspection and light microscopy; the detection of enzyme activity in transformed bacterial cells or mammalian cells using a fluorescent enzyme substrate in response to antibiotics; the detection of reporter gene expression or transformed bacteria in response to antibiotics; and the screening of animal and bacterial cell lysate by fluorescently labeled antibodies. No other working examples incorporating other cellular components, cellular responses or detector molecules were disclosed.

4. The nature of the invention is complex and unpredictable. The responses to stimuli observed in various cell types is, by its nature, varied and unpredictable. For example, Tanaka *et al.* (2004) teaches a method wherein Human Hepatoma cells show increased cell death in response to micromolar amounts of doxorubicin (Pg. 413, Fig. 3) while Smith *et al.* (2006) teaches that certain human breast cancer cells are resistant to the same compound in nanomolar amounts (Pg. 2118, Figure 1). Even among two human cell types widely divergent responses to the same chemical are observed. Predicting the responses between a fungal cell and a human neuron would be very unpredictable based upon the extreme structural and functional differences of the two cell types.

5. State of the prior art indicates that most related substances are not effective for the claimed functions. See the example above wherein the cellular response to a test compound varies between two human cell types. By extrapolation, multiple other compounds will similarly be ineffective based upon the cell makeup and type they are exposed to.

6. Level of predictability of the art is very unpredictable. See above, it would be highly improbable that one of ordinary skill in the art would be able to predict the cellular response of any cell or component thereof using any combination of detector molecule. One of ordinary skill in the art would have to construct and test every conceivable combination of cellular component with detector molecule for any possible cellular response.

7. Breadth of the claims encompasses an innumerable number of compounds. One of ordinary skill in the art would have to construct and test every conceivable combination of cellular component with detector molecule for any possible cellular response *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Also, due to the unpredictability of the chemical and biotechnological arts the extension of the test compounds (antibiotics) provided in the working examples of the specification to other inhibitors, promoters, initiators, chemicals, etc. is highly uncertain. There is no direction to determine the optimum combination and selection of compounds. Therefore, because of the large number of inoperable embodiments claimed, the ordinary artisan would be subjected to undue experimentation to practice the claimed invention. The enablement is not commensurate in scope with claims drawn to a method of assaying any cellular response from any cellular component using any detector molecule.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "cellular components" in claim 1 is used by the claim to mean "either whole cells, organisms, tissue sections or cellular vesicles or organelles ", while the accepted meaning of a component is "a constituent part" as defined by Webster's Dictionary. Therefore, the term would only properly be applied to the cellular vesicles or organelles which are constituent parts of whole cells. The term is indefinite because the specification does not clearly redefine the term.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: There is no step indicating that the detector molecules employed in Claim 1 actually detect anything and by what means the detection is effected. Claims 2-31 are rejected as being dependent upon rejected Claim 1.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the limitation "the nutrients" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 (a) refers to providing a detection agent to the cellular component. As Claim 7 is dependent upon Claim 1 which requires immobilized detector molecules, it is unclear whether two distinct means of detection are employed in one assay.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites the limitation "the cell" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 requires the cellular response be selected from a group wherein one of the chemically induced or physiological events in a cell includes surface exposure of a protein or other molecule of interest by the cell. Claim 16 defines the molecule of interest such as an antimicrobial molecules or small organic molecules including pharmaceutical molecules. It is unclear how a cell or cellular component will express either of these two compounds on its surface. Perhaps the term "molecule of interest" should be changed to "test compounds"?

No Claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Bhatia *et al.* (US 2002/0072116 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

09/26/07

JON WEBER
SUPERVISORY PATENT EXAMINER